

tion. In particular, the present invention may be practiced without perforating intact skin, or with superficial penetration or micropenetration of the skin, in contrast to the prior art which taught penetration to at least the dermis to access the vasculature (e.g., vaccination by injection with hypodermic injection). Thus, it is to be understood that modifications of and variations in the described invention will be obvious to those skilled in the art without departing from the novel aspects of the present invention and such variations are intended to come within the scope of the claims below.

[0427] Accordingly, the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments should be considered only as illustrative, not restrictive, because the scope of the present invention will be indicated by the original breadth of the appended claims rather than by the foregoing description. All modifications which come within the meaning and range of the lawful equivalency of the claims are to be embraced within their scope. In that sense, no particular order of process steps is intended unless explicitly recited.

107. The method of claim **102**, wherein pretreating comprises applying to the skin a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

108. The method of claim **102**, wherein pretreating comprises applying a chemical to the skin.

109. The method of claim **108**, wherein the chemical is an alcohol, an acetone, a detergent, a depilatory agent, a keratinolytic formulation, a cream, or a combination thereof.

110. The method of claim **102**, wherein pretreating comprises applying a device.

111. The method of claim **110**, wherein the device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an iontophoresis device.

112. The method of claim **102**, wherein the formulation consists essentially of an antigen.

SEQUENCE LISTING

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We claim:

1-101. (canceled)

102. A method for inducing an antigen-specific immune response in a subject comprising:

- a) pretreating an area of the skin of the subject by applying a means for enhancing penetration and/or bather disruption of the skin; and
- b) applying to the pretreated area a formulation comprising an antigen in an amount effective to induce a protective antigen-specific immune response and a pharmaceutically acceptable carrier, wherein the antigen is not a nucleic acid,

thereby inducing a systemic antigen-specific immune response.

103. The method of claim **102**, wherein the systemic antigen-specific immune response is primarily not an allergic reaction.

104. The method of claim **102**, wherein the systemic antigen-specific immune response comprises an antigen-specific antibody response.

105. The method of claim **102**, wherein the systemic antigen-specific antibody response comprises IgG, IgA, IgD or IgM antibody.

106. The method of claim **102**, wherein the IgG antibody comprises IgG1, IgG2a, IgG2b, IgG3 and/or IgG4.

113. The method of claim **102**, with the proviso that the formulation does not contain an adjuvant.

114. The method of claim **102**, wherein the antigen is a carbohydrate, a glycolipid, a glycoprotein, a lipid, a lipoprotein, phospholipid, a polypeptide, a protein, a fusion protein, or a chemical conjugate of a combination thereof.

115. The method of claim **102**, wherein the antigen is a whole microorganism, a whole cell, or a virion.

116. The method of claim **102**, wherein the antigen is a pathogen or is derived from a pathogen.

117. The method of claim **116**, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

118. The method of claim **117**, wherein the virus is an influenza virus or a rabies virus.

119. The method of claim **102**, wherein the antigen is hemagglutinin A.

120. The method of claim **117**, wherein the bacterium is *E. coli* or *Bacillus anthracis*.

121. The method of claim **120**, wherein the antigen is *E. coli* heat-labile enterotoxin (LT).

122. The method of claim **117**, wherein the virus is a whole virus, a live virus, an attenuated live virus, an inactivated virus, a detergent treated virus, or a combination thereof.

123. The method of claim **117**, wherein the virus is an influenza virus or a rabies virus.